K071199

BonAlive
BIOMATERIALS LTD

510(k) Summary [K071199]

Date revised: Feb 3, 2012

510(k) owner: BonAlive Biomaterials Ltd.
Turku, Finland

Contact: Ronald S. Warren
MDCI, an Aptiv Solutions company
11440 W. Bernardo Court, Suite 300
San Diego, CA 92127
United States

Device Name and Classification:
BonAlive® granules
Bone Void Filler Device, Product Code: MQV
Class II per 888.3045

Equivalent Device Identification:
NovaBone – Resorbable Bone Graft Substitute, K021336

Device Description: BonAlive® granules is a sterile medical device made of S53P4 bioactive glass. Bioactive glass is characterized by its ability to attach firmly to living tissue. Other properties include being able to guide tissue growth, bond chemically with surrounding bone in an implantation bed and promote new bone formation in the implanted area. It has been shown that tissue bonds to bioactive glass due to formation of a silica-gel layer on the glass. The silica-rich layer acts as a template for a calcium phosphate precipitation, which then bonds the bioactive glass to the surrounding bone. This makes the bioactive glass a unique material for filling defects and replacing damaged bony tissue.
The composition of this synthetic, osteoconductive material is, by weight, SiO_2 53%, Na_2O 23%, CaO 20% and P_2O_5 4%. BonAlive® granules functions in contact with body fluids allowing a progressive healing process which develops from the periphery to the central part of the obliteration mass. Best results are obtained by ensuring close contact of the device with surrounding tissue and by carefully following the instructions for clinical use.
When used in the extremities and pelvis, BonAlive® granules is intended to be used alone. BonAlive® granules is sterilized in hot dry air and available in different granule and unit sizes.

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Intended Use:
BonAlive® granules is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. BonAlive® granules is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. When used in the extremities and pelvis, BonAlive® granules is intended to be used alone. The device is not intended for use in posterolateral spine applications.

BonAlive® granules is not indicated for use in load-bearing applications, therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Determination of substantial equivalence:
BonAlive® granules is substantially equivalent to the NovaBone Resorbable Bone Graft Substitute. Both products are intended to be used as bone cavity filling materials which are packed into bone cavities of the skeletal system. Both products consist of bioactive glass with only minor differences in the composition and have been studied extensively. BonAlive® granules functions the same as NovaBone products in similar clinical applications and do not introduce any new issues of safety or effectiveness.

The biocompatibility tests showed the device was safe for the intended uses. Animal and clinical studies showed the device is a well functioning, safe and well tolerated glass material that creates suitable local environment for permanent filling of bone cavities.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 23 2012

Vivoxid Ltd.
% C.G. Bundy Associates, Inc.
Ms. Constance G. Bundy
6470 Riverview Terrace
Fridley, Minnesota 55432

Re: K071199
Trade Name: BonAlive Granules
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: January 15, 2008
Received: January 16, 2008

Dear Ms. Bundy:

This letter corrects our substantially equivalent letter of February 1, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071199

Device Name: BonAlive® granules

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
((Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K071199